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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,109	09/15/2003	Youcef M. Rustum	03551.0136	1832
26712	7590	12/05/2005	EXAMINER	
HODGSON RUSS LLP ONE M & T PLAZA SUITE 2000 BUFFALO, NY 14203-2391			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,109

Applicant(s)

RUSTUM ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,8,11 and 14 is/are rejected.
- 7) ☒ Claim(s) 2,3,9 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Sept. 15, 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to applicant's amendment received Oct. 17, 2005.

Claims 5-6, 12-13 are cancelled. No new claims are added. Claims 1-4, 7-11, 14 are currently pending.

The previous claim rejection under 35 USC 102(b) over Sieja, set forth in paragraph 2 of the office action mailed March 9, 2005 and maintained in the final rejection mailed Aug. 24, 2005, is now withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a) over Sieja in view of Stockel and El-Bayoumy, set forth in paragraph 3 of the office action mailed March 9, 2005 and maintained in the final rejection mailed Aug. 24, 2005, is now withdrawn in view of applicant's amendment and the remarks contained therein.

However, a new ground(s) of rejection follows in view of newly discovered prior art.

The finality of the office action mailed Aug. 24, 2005 is withdrawn.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 4, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sredni et al., 5,262,149.

Sredni et al. disclose a method for treating or preventing toxic alopecia, which is induced by administration of an anti-neoplastic compound (e.g. cyclophosphamide). Specifically, the method comprises administering a tellurium or selenium derivative represented by formulae (A)-(E). Alopecia associated with therapeutic doses of an anti-neoplastic agent such as cyclophosphamide can be avoided or reduced by prior, concomitant or subsequent administration of an effective amount of the tellurium or selenium compound. Please see the abstract; col. 1, line 24 to col. 2, line 34 (see also line 16, where "Q" is Te or Se); col. 5, lines 51-52. Finally, Sredni et al. teach the when administering the tellurium compound, the effective amounts range from 0.025 up to 7.5 mg/Kg of body weight. Please refer to col. 5-col. 6. When converted to $\mu\text{g}/\text{person}$, the disclosed effective amounts meet the dosage amounts in pending claims 7 and 14.

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Sredni et al. do not specifically disclose a method of treating or preventing toxic alopecia by administering a selenium compound prior, concomitant or subsequent to administration of cyclophosphamide.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select selenium for use in treating or preventing alopecia induced by cyclophosphamide because one of ordinary skill in the art would reasonably expect that the selenium compounds disclosed by Sredni et al. would have similar properties, and thus the same use as the tellurium compounds in treating or preventing alopecia induced by therapeutic use of cyclophosphamide. In other words, Sredni et al. raises reasonable expectation of success by suggesting that selenium compounds, in addition to tellurium compounds, would be effective in treating or preventing cyclophosphamide induced alopecia.

2. Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. Claims 8, 11, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sredni et al, supra in view of Rustum et al., US 2005/0026852 (102(e)=May 13, 2003).

Sredni et al. as applied above.

Sredni et al. do not disclose administering a higher than therapeutic dose of cyclophosphamide while additionally administering selenium. Yet, the examiner refers to Rustum et al., which teach that a selenium compound such as 5-methylselenocysteine (MSC) potentiates the anti-tumor activity of chemotherapeutic drugs for example, cyclophosphamide. In fact, Rustum et al. disclose that the maximum tolerated dose of these drugs is higher when

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combined with MSC since MSC protects normal tissue from drug-induced toxicity. Please see [0029]; [0061]; Example 1.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Sredni et al. by administering higher than therapeutic doses of cyclophosphamide to the cancer patients because, absent evidence to the contrary, one of ordinary skill in the art would reasonably expect the selenium compound to mitigate any toxicity associated with the higher doses. Given the teachings of Sredni and Rustum, one of ordinary skill in the art would have been motivated to increase the effective doses of cyclophosphamide with the reasonable expectation of aggressively treating the cancer while providing some comfort to the patient through the mitigation of the toxic side effects, including alopecia, associated with cyclophosphamide.

4. Claims 9-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Fakhri et al., US 2005/0197399, the effective filing date of which was determined to be the filing date of continuation-in-part application 10/844,800, May 13, 2004.

Conclusion

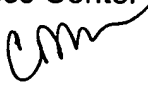
Claims 1, 4, 7, 8, 11, 14 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 
Dec. 1, 2005


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